REMARKS

Claim 18 has been amended to delete the language "wherein the scores are generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample" and to add the language "a processor means for processing data during the amplification." Thus, claim 18 has been amended to means-plus-function format. Support for this claim amendment can be found on page 2, lines 14-15 of the specification. Claim 18 has also been amended to add the phrase "for analysis of real-time amplification of." Support for this claim amendment can be found throughout the specification, for example, in the title and on page 13, lines 22-23 of the specification. Claim 18 has also been amended to add the word "the" to the phrase "a fluorimeter for detecting fluorescence during the amplification."

Applicants wish to thank Examiner Smith for the courtesies extended by the Examiner in the telephonic interview with Applicants' undersigned attorney on February 23, 2005. An agreement was not reached with respect to allowance of the claims, but it is Applicants' understanding that the Examiner will consider the arguments made in the interview in view of the amendments made in this response and the arguments discussed in this response.

The Examiner has rejected claims 18-23 under 35 U.S.C. § 112, ¶ 1 for lack of a written description. The Examiner indicates that the claim amendment made in the response to the office action mailed on May 11, 2004, to amend claim 18 to add the language "wherein the scores are generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample" constitutes new matter.

Applicants do not agree. There is support for this language in the specification, for example, on page 2, lines 14-15 of the application. Although Applicants do

not agree that the specification lacks written description support for claim 18, as previously amended, Applicants have deleted the language objected to by the Examiner. Applicants have amended claim 18 to specify "a processor means for processing data during the amplification." This language has written description support on page 2, lines 14-15 of the specification which states that "data processing can occur during amplification" and that "initiation of the analysis algorithm can be implemented prior to completion of temperature cycling." As also indicated by the Examiner (see page 3, lines 10-11 of the October 22 office action), the application states that the "fluorescent data were acquired during amplification." Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 112, ¶ 1 is respectfully requested.

The Examiner has also rejected claims 18-23 under 35 U.S.C. § 102(a) and 102(e) as being anticipated by Schork et al. (U.S. Patent No. 6,291,182; hereinafter the '182 patent). Applicants respectfully traverse the Examiner's rejection. The '182 patent does not anticipate claim 18, as amended, or its dependent claims 19-23.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Claim 18 of the above-captioned application specifies "a processor means for processing data during the amplification" to clarify that a structural characteristic of the claimed device is that the processor is programmed to analyze data during amplification of the nucleic acids. Again, as stated in the specification, "initiation of the analysis algorithm can be implemented prior to completion of temperature cycling" and "data processing can occur during amplification." The '182 patent does not describe a processor that analyzes data during amplification of nucleic acids to ascertain whether the nucleic acid is present in the sample.

The Examiner indicates that the '182 patent discloses a fluorimeter and Picogreen to determine quantities of amplification products and refers to column 47, lines 7-9 of the '182 patent (Example 6). However, although Example 6 discloses a fluorimeter and the use of Picogreen to quantitate nucleic acids, the fluorimeter and Picogreen are used to determine quantities of amplification products after amplification is complete in samples from the amplification reaction after final elongation that are aliquoted into 96-well plates. Thus, the quantities of amplification products are determined after the amplification reaction is complete (see column 47, lines 1-9).

The Examiner also refers to the sequencing method described in Example 6 and indicates that the '182 patent discloses the use of dideoxy terminator sequencing reactions to determine sequences of amplification products wherein the sequence data is evaluated using software designed to detect sites among the amplified products via different fluorescent molecules and by evaluating intensity ratios. The Examiner refers to column 47, lines 10-15 and column 47, lines 10-28 in Example 6 of the '182 patent. However, the sequencing reactions described in Example 6 of the '182 patent are done using dideoxy terminators, each labeled with a different fluorescent molecule, and the sequences are analyzed by running the products of the sequencing reaction on sequencing gels and then using gel image analysis of the sequencing gels to determine the sequences (see column 47, lines 11-36). According to the Examiner, the "fluorescence measurement" in this sequencing protocol is the gel image analysis that is used to determine the sequence. The sequence data from the gel image analysis is then evaluated using software designed to detect the presence of a nucleic acid in a sample. Thus, the fluorescence measurement that is related to the sequencing protocol described in Example 6 is not done during amplification of the nucleic acid. Rather the gel image analysis (*i.e.*, the fluorescence measurement) is done on samples run on a sequencing gel and the samples are run on the sequencing gel after amplification is

complete. A similar method is described in Example 17 and is also referred to by the Examiner.

The Examiner indicates that the broadest reasonable interpretation of Applicants' claims can be used by the Examiner to interpret the claims and to make rejections over the prior art. The Examiner indicates that she has reasonably interpreted the claims to "include many steps, including steps involving amplified products." Contrary to the Examiner's interpretation, it would be very clear to a person skilled in the art of molecular biology that the phrase "during amplification" means only steps that occur during the polymerase chain reaction and does not mean amplified products after the polymerase chain reaction has been completed.

Moreover, the Examiner's interpretation of the phrase "during amplification" as including steps involving amplified products after amplification is complete is not reasonable in light of the specification. The purpose of the invention, as described on page 2, lines 3-18 of the specification, is to process data during the amplification reaction, as opposed to prior art instrumentation that processes data after the amplification reaction is complete. As indicated on page 2, lines 5-6 of the specification, the present invention is distinguished from prior art instrumentation which "does not actually analyze data during PCR; it simply acquires the data for later analysis." Accordingly, the Examiner's broad interpretation of the claims, as including data analysis on amplified products after the polymerase chain reaction is complete, is not a reasonable interpretation in light of the specification.

Furthermore, claim 18 has been amended to specify "a processor means for processing data during the amplification." The phrase "during the amplification" has antecedent basis in the phrase "an instrument for temperature cycling for analysis of real-time amplification of the nucleic acid." Accordingly, in claim 18, as amended, "during the amplification" cannot include amplified PCR products after the amplification reaction is

complete because the phrase "during the amplification" has antecedent basis in the phrase "an instrument for temperature cycling for analysis of real-time amplification of the nucleic acid" and "real-time amplification" necessarily means during the amplification reaction.

The '182 patent describes only data collection for samples that have been aliquoted into a microtiter plate and are no longer undergoing the polymerase chain reaction (as described in Example 6 of the '182 patent) or samples that are being run on a sequencing gel and are no longer undergoing the polymerase chain reaction (as described in Examples 6 and 17 of the '182 patent). Accordingly, for the devices and methods described in the '182 patent, the fluorescence measurements are done after the amplification reaction has been completed and the analysis of the data generated from the fluorescence measurements is done after amplification of the nucleic acids has been completed. No where does the '182 patent describe a processor means for processing data during the amplification of nucleic acids. Thus, the '182 patent does not describe all of the required elements of claims 18-23 and the '182 patent cannot anticipate claims 18-23.

The Examiner contended in the Advisory Action mailed on February 15, 2005 and in the interview with Applicants' undersigned attorney that the phrase "to process the scores during amplification" as specified in amended claim 18 in Applicants' response filed on January 24, 2005, is functional language that does not have patentable significance in a device claim. Claim 18 has been amended to means-plus-function format. As stated in *Acromed Corporation v. Sofamor Danek Group, Inc.*, "[w]hen a patentee elects to claim his invention using "means-plus-function" language, the final step requires identifying the minimal function required by the claim and identifying the corresponding structure in the specification . . . ". *Acromed Corporation v. Sofamor Danek Group, Inc.*, 23 F.3d 1371 (Fed. Cir. 2001). Accordingly, a claim with means-plus-function language requires functional language in the claim, and the claim is properly construed to cover the

corresponding structure in the specification and equivalents thereof. Based on all of the above arguments, withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 102(a) and 102(e) is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejection. The amended claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,

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